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Eye movement desensitization and reprocessing therapy in subsyndromal bipolar patients with a history of traumatic events: A randomized, controlled pilot-study

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ABSTRACT

Traumatic events are frequent in bipolar patients and can worsen the course of the disease. Psychotherapeutic interventions for these events have not been studied so far. Twenty DSM-IV bipolar I and II patients with subsyndromal mood symptoms and a history of traumatic events were randomly assigned to Eye Movement Desensitization and Reprocessing therapy ($n=10$) or treatment as usual ($n=10$). The treatment group received between 14 and 18 Eye Movement Desensitization and Reprocessing sessions during 12 weeks. Evaluations of affective symptoms, symptoms of trauma and trauma impact were carried out by a blind rater at baseline, 2 weeks, 5 weeks, 8 weeks, 12 weeks and at 24 weeks follow-up. Patients in the treatment group showed a statistically significant improvement in depressive and hypomanic symptoms, symptoms of trauma and trauma impact compared to the treatment as usual group after intervention. This effect was only partly maintained in trauma impact at the 24 weeks follow-up visit. One patient dropped from Eye Movement Desensitization and Reprocessing group whereas four from the treatment as usual group. This pilot study suggests that Eye Movement Desensitization and Reprocessing therapy may be an effective and safe intervention to treat subsyndromal mood and trauma symptoms in traumatized bipolar patients.

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1. Introduction

Traumatic events include early childhood adversities and negative life events during the later life, both of which are experienced frequently by patients with bipolar disorder (Johnson et al., 2008; Post et al., 2013). Not surprisingly, traumatic events often lead to the diagnosis of post-traumatic stress disorder (PTSD) with symptoms, such as flashbacks, feeling emotionally numb, loss of interests, being easily startled or sleeping problems. PTSD is highly comorbid in adult bipolar disorder as suggested by findings from the STEP-BD study of 3158 bipolar patients with an overall prevalence rate of 20% for lifetime PTSD, a rate that is roughly three times its lifetime

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prevalence in the general population (Hernandez et al., 2013). This comorbidity is associated with a poorer outcome with more rapid-cycling, more (hypo)manic and depressive symptoms, more suicide attempts and substance abuse and a lower quality of life, when compared to bipolar patients without PTSD (Goodman et al., 2001; Quarantini et al., 2010). Same clinical consequences have also been found in populations with bipolar disorder and a history of traumatic events, not meeting necessarily criteria for PTSD (Goodman et al., 1997; Mueser et al., 1998; Etain et al., 2013). The comorbidity of traumatic events/PTSD and bipolar disorder may also negatively impact on response to treatment as trauma related avoidance with further social isolation, anxiety and depressive symptoms worsen affective symptoms (Cresswell et al., 1992; McElroy, 2004).

The evidence of negative effects of traumatic events or PTSD on the course of bipolar disorder is robust but no treatment trials have been directed so far to this comorbidity. One form of treatment which is increasingly used in PTSD is Eye Movement Desensitization and

Reprocessing (EMDR) therapy (Shapiro, 2001). This form of psychotherapy uses a standardized eight phase protocol which involves making side-to-side eye movements while simultaneously focusing on symptoms and experiences related to the traumatic event; the approach also incorporates elements of cognitive behavioral, interpersonal, and body-centered therapies (Shapiro, 1999, 2001). Three independent meta-analyses have found Eye Movement Desensitization and Reprocessing therapy to be effective in PTSD, with benefits similar to trauma-focused cognitive behavioral therapy (Seidler and Wagner, 2006; Bisson et al., 2013; Watts et al., 2013).

The usefulness of Eye Movement Desensitization and Reprocessing therapy has not so far been investigated in bipolar disorder. The aim of this pilot trial was to evaluate whether Eye Movement Desensitization and Reprocessing therapy can have mood stabilizing effects in bipolar patients with mild depressive and/or hypomanic symptoms, called subsyndromal symptoms (Tohen et al., 2009). We chose subsyndromal symptoms as they are clinically relevant by causing more affective relapses and poor functioning (Altschuler et al., 2006; Judd et al., 2008). Furthermore, bipolar patients would be also more likely to be able to tolerate and benefit from Eye Movement Desensitization and Reprocessing therapy than those who were currently experiencing a moderate to full-blown depressive or manic/mixed episode. We hypothesized a mood-stabilizing effect of Eye Movement Desensitization and Reprocessing therapy via processing the trauma as (1) bipolar patients with trauma –as stated above– suffer from more affective symptoms than bipolar patients without trauma (e.g. Leverich and Post, 2006; Quarantini et al., 2010), and (2) preliminary results suggest that Eye Movement Desensitization and Reprocessing therapy develops mood-stabilizing properties via the modulation of the Default Mode Network which is dysfunctional in both PTSD and bipolar disorder (Landin-Romero et al., 2013).

2. Methods

2.1. Study design

The study was designed as a single-blind, randomized, controlled trial to evaluate the efficacy of Eye Movement Desensitization and Reprocessing therapy as an adjunctive treatment in bipolar patients with subsyndromal symptoms and a history of traumatic events. Participants were randomly assigned to 12 weeks of treatment with Eye Movement Desensitization and Reprocessing therapy or treatment as usual. The participants were re-assessed at the end of this period and also after a further 12 weeks of follow-up which was considered sufficient to test whether possible effects of Eye Movement Desensitization and Reprocessing therapy were maintained or not. The primary outcome measures were depression and mania ratings. Secondary outcome criteria included changes in trauma scales and safety aspects of Eye Movement Desensitization and Reprocessing therapy. A priori participants were considered as drop-outs if they withdrew their informed consent or developed a full blown affective episode.

The investigation was carried out in accordance with the latest version of the Declaration of Helsinki, the study design was reviewed by the ethical committee “Comité Ético de Investigación Clínica de las Hermanas Hospitalarias” (Barcelona, Spain) and written informed consent of the participants was obtained after the nature of the procedures had been fully explained. All participants were also informed in case of their non participation that this has no direct or indirect influence or consequence on their usual treatment.

The trial was registered in ClinicalTrials.gov (NCT01620866).

2.2. Subjects

Participants were recruited from September 2010 through July 2011 from the outpatient unit of a psychiatric hospital (Benito Menni CASM, Sant Boi de Llobregat, Spain). Last follow-up ended accordingly in December 2011. To be included, all participants were required to have a diagnosis of bipolar disorder I or II according to DSM-IV criteria. They were also required to show subsyndromal affective symptoms, defined following the International Society for Bipolar Disorder criteria (Tohen et al., 2009) as scores of $> 8 < 14$ on the Hamilton Depression Rating Scale (HDRS; Hamilton, 1960), or $> 8 < 14$ on the Young Mania Rating Scale (YMRS; Young et al., 1978). The participants were also required to be on stable doses of mood-stabilizers for at least 3 months. Furthermore, all participants had to have experienced at least three documentable traumatic events over their lifetime, which were still causing a clinically relevant distress. This was defined as a score of at least five or more Subjective Units of

Disturbance, known as SUD, usually used in the Eye Movement Desensitization and Reprocessing standard protocol (scores from 0 to 10, with 10 being of maximum disturbance). The traumatic events and their current impact were determined using the Clinician-Administered PTSD Scale (CAPS; Blake et al., 1995) and the Impact of Event Scale (IES; Weiss and Marmar, 1997) (see details below).

Participants were excluded if they had a history of neurological disease or abuse/dependency on alcohol or drugs. Suicidality, an affective episode in the last 3 months, previous Eye Movement Desensitization and Reprocessing treatment and a score higher than 25 in the Dissociative Experiences Scale (DES; Bernstein and Putnam, 1986) were further exclusion criteria. The rationale for this last exclusion was that a more extensive Eye Movement Desensitization and Reprocessing protocol (beyond the standard eight phase Eye Movement Desensitization and Reprocessing protocol) is recommended when dissociative symptoms are present.

2.3. Procedure

Participants were allocated by the senior author (BLA) to Eye Movement Desensitization and Reprocessing therapy or treatment as usual by alternation. They were evaluated at 6 time-points, baseline, 2 weeks, 5 weeks, 8 weeks, 12 weeks, and then again at 24 weeks.

The participants who were assigned to Eye Movement Desensitization and Reprocessing therapy were allocated to one of nine Eye Movement Desensitization and Reprocessing therapists. All therapists had more than 10 years experience with Eye Movement Desensitization and Reprocessing therapy. Each of them discussed their patient with all the other therapists and they jointly defined the main targets for the trauma therapy. Eye Movement Desensitization and Reprocessing treatment followed the standard protocol of eight phases developed by Shapiro (Shapiro, 1999, 2001). All participants received between 14 and 18 individual sessions, lasting 90 min over a period of 12 weeks. The criterion for completion of Eye Movement Desensitization and Reprocessing therapy was attendance at all therapy sessions during 12 weeks.

All sessions were video-taped and a fidelity check was made by an external Eye Movement Desensitization and Reprocessing therapist (IF) who randomly selected 10 sessions and evaluated if therapists followed the procedure and the targets of the Eye Movement Desensitization and Reprocessing standard protocol. All selected videos were positively rated as such. Participants in the treatment as usual group continued to receive standard outpatient care from their treating psychiatrists.

2.4. Assessments

All participants were evaluated by a single assessor (VV), a psychiatrist who was not otherwise involved in the study. He was not trained in Eye Movement Desensitization and Reprocessing and had no allegiance to this form of psychotherapy. The assessor was unaware of treatment allocation and the participants were instructed not to reveal their treatment group to him.

To assess affective symptoms, the HDRS and the YMRS were used, plus the Clinical Global Impression-Bipolar Disorder (CGI-BP; Spearing et al., 1997). The CGI-BP is divided into subscales for manic (CGI-BP-m) and depressive symptoms (CGI-BP-d) and general symptoms (CGI-BP-g). Participants were evaluated on these scales at baseline, 2 weeks, 5 weeks, 8 weeks, 12 weeks and 24 weeks.

The two trauma scales, the IES-R (Weiss and Marmar, 1997) and the CAPS (Blake et al., 1995), were administered at baseline, after 12 weeks and 24 weeks. The CAPS is a 30-item structured interview that assesses the seventeen symptoms for PTSD outlined in the DSM-IV, along with five associated features. It can be used to make a current (past month) or lifetime diagnosis of PTSD or to assess symptoms over the past week. Additionally, questions target on improvement in symptoms since the previous CAPS administration, overall PTSD severity and frequency. Severity scores can be also calculated by summing the frequency and intensity ratings for each symptom. The IES-R is a 22-item self-report measure that assesses subjective distress caused by traumatic events. Patients are asked to identify a specific stressful life event and then indicate how much they were distressed or bothered by it during the past seven days. Items are rated on a 5-point scale ranging from 0 (“not at all”) to 4 (“extremely”). The IES-R yields a total score (ranging from 0 to 88) and scores can also be calculated on Intrusion, Avoidance, and Hyperarousal subscales. Subscale scores can be weighted on a component score to calculate the likelihood of a PTSD diagnosis. The closer to 0, the more likely is the diagnosis of PTSD. As participants had to present with at least three disturbing traumatic events in the history, we evaluated the trauma impact of each of them separately: IES 1, IES 2 and IES 3.

Premorbid IQ was estimated using the Word Accentuation Test [Test de Acentuación de Palabras, TAP (Del Ser et al., 1997; Gomar et al., 2011)], a word reading test which requires pronunciation of low-frequency Spanish words whose accents have been removed. Current IQ was measured using four subtests of the Spanish version of the Wechsler Adult Intelligence Scale III (WAIS-III), Vocabulary, Similarities, Matrix Reasoning, and Block Design. Raw scores were converted into scaled scores for the relevant age group, and then prorated to calculate full-scale IQ.

2.5. Statistical analysis

This study was designed as a pilot trial and thus it did not include formal sample size estimation. A total number of 20 participants was considered as

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